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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BROWN, COURTNEY A	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,840	WYNN ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-15,17-21 and 24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-15,17-21 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed March 20, 2009. Claims **1, 3-6, 9-15, 17-21, and 24-30** are pending in the application. Claims **2,7,8,16,22 and 23** have been cancelled. Claims **1,17,18 and 21** have been amended.. Claims **1, 3-6, 9-15, 17-21, and 24-30** are being examined for patentability.

Applicant's arguments, see pages 7-10, filed March 30, 2009, with respect to the rejection(s) of claim(s) **1,3-6,9-21 and 24-30** under 35 USC 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made below.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on June 3, 2009 has been considered by the examiner.

The objection of claims 1 and 4 has been **maintained.**

Claim Objection(s)

The Examiner has observed that claim 1, line 4 states "wherein said controlled release composition is comprises" and should state "wherein said controlled release composition is comprised". Appropriate action is required.

Response to Arguments

In the Arguments filed March 30, 2009, Applicant did not address the aforementioned objection. Appropriate action is required.

The obviousness-type double patenting rejection of claims 1, 4, and 9-12 over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967). **is maintained.**

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application10/697,546.

Copending claims 13-15, 19 and 26 and instant claims 1,4 and 9-12 teach the same liquid suspension dosage form comprising: a.) particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming polymer and an enteric polymer and the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1 and b.) a vehicle for the administration of the particles comprising water or mixtures of water and a pharmaceutically acceptable water-miscible co solvent selected from the group

consisting of glycols, alcohols, and glycerol. The difference between the invention of the instant application and that of copending Application No. 10/697,546 is that the instant application claims a liquid suspension comprising only a controlled release composition as opposed to a liquid suspension comprising a controlled release composition and an immediate release composition. Clemente et al. teach that an extended release formulation can be extremely beneficial at night, so that a child can rest or sleep comfortably for a sufficiently long period of time while under the effects of the analgesic (acetaminophen) if the child is in pain, or under the effects of the antipyretic if the child is febrile(column 20, lines 25-36). One would have been motivated to make this combination in order to receive the expected benefit of having pharmaceutically acceptable liquid suspension system that has a therapeutic effect over an extended period of time without exposing the patient such as a child to a large amount of active compound. From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 10/697,546.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to hold in abeyance the nonstatutory obviousness-type double patenting rejection of claims 1,4 and 9-12 over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967) is acknowledged. However, the nonstatutory obviousness-type double patenting rejection has been maintained until claims are in condition for allowance.

New Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-15, 17-21, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US Patent 6,126,969, cited in the Office Action filed January 12, 2009) in combination with Singh et al. (US Patent 5,759,579,cited in the Office Action filed January 12, 2009) in view of Sakamoto et al. (US Patent 4,828,840).

Applicant's Invention

Applicant claims a pharmaceutical liquid suspension dosage form comprising: a). particles of an NSAID and/or acetaminophen, wherein 99% of said particles are covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming polymer and an enteric

polymer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1; and

b). a vehicle for the administration of the particles comprising water, wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least 8 hours after its initial administration to a mammal.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Shah et al. teach a dosage form comprising an extended releasing portion (abstract). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col. 5, lines15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lines 40-58). The active agents include various well-known drugs including acetaminophen (tables 1 and 2). Shah et al. teach that the formulation can be dispersed in water in order to form a suspension (col. 4, lines 15-17). In the first embodiment, Shah et al. teach a formulation comprising only a sustained release formulation (column 2, lines 58-end bridging to column 3 and column 4, lines 1-29). Thus, according to this particular embodiment of Shah et al., at least 99% of the actives are covered with one layer of a controlled release composition.

Singh et al. teaches a pharmaceutically acceptable liquid suspension system provided for solid finely divided pharmaceutical actives such as antihistamines,

decongestants, antitussives, expectorants, non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen and phenacetin(column 2, lines 30-43), ibuprofen, naproxen, and ketoprofen (column 3, lines 12-15). The suspension system comprises water, xanthan gum and hydroxypropyl methylcellulose (abstract). Singh teaches the use of excipients known to the art including humectants such as glycerin and propylene glycol, preservatives such as sodium benzoate and paraben, sweeteners such as sodium saccharin, corn syrup and sorbitol solutions, menthol and various flavoring and coloring agents (column 4,lines 5-9). Singh teaches various examples of liquid suspension systems in columns 4-7 wherein the concentrations of the drug is about 3.2 % and the water content is at least 40%.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the invention of the instant application and that of Shah et al. and Singh et al. is that the instant invention claims the use of particles of NSAID and/ or acetaminophen wherein said particles are covered with a controlled released composition comprising one layer of an insoluble film forming polymer and an enteric polymer in a weight ratio of about 80:20 to about 99:1 wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least 12 hours. For this reason, the teaching of Sakamoto et al. is joined. Sakamoto et al. teach a controlled release formulation comprising a coated dosage form wherein the coating comprises a combination of water-insoluble polymers and enteric polymers

(abstract). The formulation can last for longer than 10 hours) (col. 2, lines 30-35) and can comprise a wide range of active agents. The film coating comprises water-insoluble polymers such as cellulose acetate, ethyl cellulose and copolymers of polymethacrylate and trimethylammoniummethyl chloride methacrylate sold as Eudragit RS (col. 4, lines 5-15). The enteric polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate acetate and copolymers of methacrylic acid and polymethyl methacrylate (col. 4, lines 16-25). The water-insoluble polymers are combined together (see column 2, lines 62-end bridging to column 3, lines 1-7) with the enteric polymers to form an extended release coating where the insoluble polymer is present in a ratio to the enteric polymer of 8.7:1 (see example 13) which is within the limits of the instant claims.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen being substantially covered with one layer of a controlled release composition. Shah et al. teach an orally administrable sustained-release dosage form and suggests that said sustained-release dosage form can be dispersed into water in the form of suspension (column 4, lines 14-17 of Shah et al.). It would have been obvious to modify the ratio of polymers in the extended coating of Shah et al. as taught

by Sakamoto et al. in order to deliver a stable drug release over an extended period of time, at least 12 hours. It would have been obvious to combine the teachings of Singh et al. , Shah et al., and Sakamoto et al. with an expected result of a stable controlled release formulation in the form of a suspension.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments, filed March 30, 2009, with respect to the 35 USC 112 second paragraph rejections of claims 1, 12, 15,17,18,20, and 21 have been considered but are moot in view of a new ground of rejection.

Applicant's arguments, filed March 30, 2009, with respect to the 103 rejection of claims 1, 3-6, 9-21, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US Patent 6,126,969) in view of Singh et al. (US Patent 5,759,579) and Clemente et al (US Patent 6,126,967) have been considered but are moot in view of the new ground(s) of rejection.

The claims remain rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown
Patent Examiner
Technology Center1600
Group Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616